

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

In re MIRAPEX PRODUCTS LIABILITY
LITIGATION

MDL No.: 07-1836 (JMR/FLN)

This document relates to

ANTHONY SCELTA,

Civil No. 08-cv-5067 (JMR/FLN)

Plaintiff,

vs.

BOEHRINGER INGELHEIM
PHARMACEUTICAL, INC., a Delaware
corporation, PFIZER INC., a Delaware
corporation, PHARMACIA
CORPORATION, a Delaware corporation,
and PHARMACIA & UPJOHN
COMPANY LLC,

**MEMORANDUM OF LAW IN
SUPPORT OF DEFENDANTS'
JOINT MOTION TO EXCLUDE
THE EXPERT TESTIMONY OF
HEATHER CHAPMAN, PhD.**

Defendants.

Defendants Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), Pfizer Inc., and two Pfizer subsidiaries, Pharmacia Corporation and Pharmacia & Upjohn Company LLC (collectively, “Pfizer”) offer this memorandum in support of their joint motion to exclude the testimony of Plaintiff’s expert general and specific causation witness, Heather Chapman, Ph.D.

I. INTRODUCTION

Plaintiff alleges that he developed hypersexuality three weeks after starting Mirapex in 2005. As his general and specific causation expert, Plaintiff has

proffered Heather Chapman, Ph.D., a psychologist who specializes in the treatment of pathological gambling.

Dr. Chapman cannot be permitted to testify on the issue of general causation because she is unable to say that the scientific evidence shows that Mirapex causes hypersexuality. Instead, she will only say that there is an association between Mirapex use and hypersexuality.

For two reasons, Dr. Chapman is not qualified under Rule 702 to give a specific causation opinion. First, this is not a gambling case. Although Dr. Chapman may have some expertise in one type of compulsive behavior – gambling – such expertise does not qualify her as an expert on other compulsive behaviors. Indeed, Dr. Chapman testified that she is not qualified to diagnose a patient with hypersexuality. Second, because she is a psychologist and not a medical doctor, Dr. Chapman is not qualified to offer an opinion that an agent caused a specific patient's disease.

For a number of reasons, Dr. Chapman's specific causation opinion does not meet the *Daubert* standard for reliability and is therefore inadmissible. First, Dr. Chapman's methodology for determining Plaintiff suffered from hypersexuality – an Internet questionnaire on the website “www.SexHelp.com” – does not meet any of the *Daubert* factors for reliability. Second, Dr. Chapman was forced to render her opinion based solely on Plaintiff's own account of his experience on Mirapex because Plaintiff failed to comply with Dr. Chapman's numerous requests for access to medical records and other information. Finally,

Dr. Chapman does not account for the fact that although Plaintiff claims that he developed hypersexuality three weeks after starting Mirapex in 2005, a six- week regimen of Mirapex at the same dose in 2001 did not cause him to develop any compulsive behaviors, including hypersexuality.

II. ARGUMENT

A. Dr. Chapman cannot testify on general causation because she is unable to say that Mirapex causes hypersexuality.

A plaintiff alleging that an agent caused his disease must show both “general causation” and “specific causation.” *Haller v. Astrazeneca Pharmaceuticals, LP* 598 F. Supp. 2d 1271, 1275 (M.D. Fla. 2009). General causation “bears on whether the type of injury at issue can be caused or exacerbated by the defendant’s product,” while specific causation “bears on whether, in the particular instance, the injury actually was caused or exacerbated by the defendant’s product.” *In re Viagra Products Liability Litigation*, 572 F. Supp. 2d 1071, 1076 (D. Minn. 2008) (citation omitted). A plaintiff must prove causation “with reasonable medical probability,” *Colville v. Pharmacia & Upjohn Company LLC*, 565 F. Supp. 2d 1314, 1322 (N.D. Fla. 2008), and does not meet this burden by showing merely that there is an association between an agent and a disease. Federal Judicial Center, *Reference Manual on Scientific Evidence* 336 (2d ed. 2000) (“it should be emphasized that *an association is not equivalent to causation*”); *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1315 n.16 (11th Cir. 1999) (“[s]howing *association* is far removed from proving *causation*”). See also

Ex. 1, Chapman Dep. 96 (“Q: All right. And a mere association, however, does not necessarily mean that the association is causal in nature? A: That’s true.”).¹

Dr. Chapman testified that she does not hold the opinion that the scientific evidence establishes that Mirapex causes hypersexuality. Instead, she testified only that there is an association between Mirapex and hypersexuality.

Q: So, in this case, Doctor, just so I understand, are you really just saying that when you look at the case reports and the other fragmentary pieces of evidence that you have referred to, that there appears to be an association between Mirapex and gambling and hypersexuality?

A: Absolutely.

Q: Okay. Are you prepared to take it further than just saying there is an association?

A: It’s difficult to state causation.

Q: You are not stating causation then?

A: Well, you can’t state causation.

(Chapman Dep. 137). *See also id.* at 251 (“Q: . . . well, I think what we’ve established today is in fact that you are not making a causation claim, you are saying that it has been associated through the various studies we’ve talked about, right? A: Yes.”).

¹ All defense exhibits are to the attached affidavit of Scott A. Smith.

In sum, Dr. Chapman does not hold the opinion that general causation has been established.² As a result, she should not be permitted to testify on the issue of general causation.

B. Dr. Chapman's expertise in pathological gambling does not qualify her to diagnose Plaintiff as suffering from hypersexuality.

Dr. Chapman's claimed expertise is in the treatment of pathological gambling. (Ex. 2, Chapman CV). However, Dr. Chapman is not offering an opinion that Plaintiff suffered from pathological gambling. (Chapman Dep. 72, 164-65). Instead, she claims that Plaintiff suffered from hypersexuality. (Chapman Dep. 72). But, by her own admission, Dr. Chapman is not qualified to diagnose a patient as suffering from hypersexuality. She testified that she is qualified to diagnose patients only with disorders listed in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-IV"), and that the DSM-IV does not recognize the condition of hypersexuality. (Chapman Dep. 9-10, 24). Moreover, Dr. Chapman's CV makes no reference to diagnosing patients with hypersexuality, and she has not published any peer reviewed articles on hypersexuality or given any presentations on hypersexuality. (Chapman Dep. 14-15).³

² Even if Dr. Chapman opined that general causation had been established, her opinion would be inadmissible because she does not offer a sufficient basis for such an opinion. See *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 989-91 (8th Cir. 2001).

³ Plaintiff alleges that his hypersexuality caused him to engage in excessive spending (*e.g.*, spending on prostitutes, Internet pornography, *etc.*). The DSM-IV

While Dr. Chapman may be an expert on pathological gambling, such expertise does not qualify her as an expert on all other compulsive behaviors. “The fact that a proposed witness is an expert in one area, does not *ipso facto* qualify him to testify as an expert in all related areas.” *Travelers Prop. Cas. Co. v. National Union Ins. Co.*, 557 F. Supp. 2d 1040, 1048 (W.D. Mo. 2008) (collecting cases). In sum, Dr. Chapman is not qualified to offer an opinion that Plaintiff suffered from hypersexuality.

C. Because Dr. Chapman is a psychologist, and not a medical doctor, she is not qualified to render an opinion on specific causation.

Dr. Chapman is a psychologist, not a medical doctor. Courts have recognized that the question of whether an agent caused a specific patient’s disease is a medical issue, and that because a psychologist is not a medical doctor, a psychologist is not qualified to render an opinion on whether exposure to an agent caused a patient’s disease. See *Mancusco v. Consolidated Edison Co. of New York*, 967 F. Supp. 1437, 1440, 1456-57 (S.D.N.Y. 1997) (where psychologist was not a medical doctor, he was not qualified to render opinion that exposure to an agent caused plaintiff’s behavioral problems and learning disability); *Summers v. Missouri Pacific R.R. System*, 897 F. Supp. 533, 540 (E.D. Okla. 1995) (excluding causation testimony by psychologist because “the question of causation is a medical issue” and the psychologist was “not an expert in the

does not recognize the condition of compulsive spending, and Dr. Chapman conceded that compulsive spending “is not a classified disorder” and that “[t]here is no diagnostic criteria for” compulsive spending. (Chapman Dep. 245). As a result, Dr. Chapman is not qualified to diagnose plaintiff as a compulsive spender.

field of medicine or toxicology").⁴ Indeed, Dr. Chapman admitted that outside of litigation, she has never been called upon to determine whether an agent caused an outcome. (Chapman Dep. 33-34). In sum, Dr. Chapman's expertise in psychology does not qualify her to render an opinion on whether Mirapex caused Plaintiff's alleged hypersexuality.

D. Dr. Chapman's methodology for determining that Plaintiff suffered from hypersexuality (an Internet questionnaire on "SexHelp.com") does not meet the *Daubert* reliability requirement.

In order to determine whether Plaintiff suffered from hypersexuality in 2005, Dr. Chapman had Plaintiff fill out a questionnaire on the website www.SexHelp.com. (Chapman Dep. 167-72; Exs. 3-4, website printouts). Dr. Chapman directed Plaintiff to answer the questions based on his recollection of his behavior in the summer of 2005. (Chapman Dep. 171). Dr. Chapman did not analyze Plaintiff's answers to the questionnaire. Instead, the website's software determined that Plaintiff's answers for the summer of 2005 "indicate[d] sex addiction." (Ex. 3). However, neither Plaintiff nor Dr. Chapman have established that relying on a website to diagnose a patient with hypersexuality is a reliable methodology under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006) ("The burden is on the party offering the expert testimony to prove that it is reliable.").

⁴ See also *Sanderson v. IFF*, 950 F. Supp. 981, 986, 1001 (C.D. Cal. 1996) (neuropsychologist was not qualified to offer opinion that exposure to perfume and cologne caused brain damage and deranged sense of smell; "a neuropsychologist . . . is not a qualified expert on issues of toxic causation").

Specifically, neither Plaintiff nor Dr. Chapman have offered any evidence on whether use of this questionnaire meets the reliability factors set out in *Daubert*.⁵ Indeed, Dr. Chapman conceded that she does not know whether the questionnaire has ever been validated for determining whether someone was addicted to sex during a previous time period. (Chapman Dep. 171) (“Q: All right. Has this screening test been validated for past sexual behavior? A: I do not know that.”).

See Daubert, 509 U.S. at 593 (“a key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested”).⁶

E. Dr. Chapman’s specific causation opinion is unreliable because, by Dr. Chapman’s own admission, Plaintiff has withheld key information from her.

Dr. Chapman testified that her specific causation opinion was based only on what Plaintiff told her about his experience with Mirapex. *See* Chapman Dep. at 166 (“The only thing I had to go by is his self-report.”); 207 (“I wrote a report that

⁵ Those factors are: “(1) whether the theory ‘can be (and has been) tested,’ (2) whether the theory ‘has been subjected to peer review and publication,’ (3) ‘the known or potential rate of error,’ and (4) whether the theory enjoys general acceptance in the relevant scientific community.” *Wagner*, 450 F.3d at 758.

⁶ Dr. Chapman also had Plaintiff complete an “NEO-Personality Inventory” for 2005 and for 2009, and claimed that the results from these tests showed that Plaintiff had “higher levels of impulsivity” in 2005 than he does today. (Chapman Dep. 218-221). However, Dr. Chapman did not produce in her report or at her deposition any records or data from these tests. (Ex. 5, Chapman Report; Chapman Dep. 220). *See* Fed. R. Civ. Pro. 26(a)(2)(B)(ii) (expert report shall include “the data” considered by the expert in forming her opinion). Moreover, she conceded that the NEO-Personality Inventory has not been validated for retrospective evaluations and that “it is not designed to be used” for retrospective evaluations. (Chapman Dep. 219).

was based on his report to me and the literature and that's it.”). But, it is well-settled that the “self-reporting of a plaintiff’s medical history in preparation for litigation, without additional independent confirmation, is inherently unreliable.” *Goeb v. Tharaldson*, 615 N.W.2d 800, 816 (Minn. 2000); *see also In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 762 (3rd. Cir. 1994) (“a physician who evaluates a patient in preparation for litigation should seek more than a patient’s self-report of symptoms or illness”); *Miller v. United States*, 422 F. Supp. 2d 441 (D. Del. 2006) (specific causation expert’s opinion was unreliable where expert relied on plaintiff’s self-report rather than reviewing all of plaintiff’s medical records).

Indeed, Dr. Chapman all but conceded that she did not have sufficient information on which to base a specific causation opinion. Throughout her deposition, she noted that Plaintiff had refused to provide her with access to records and other information that she felt were necessary to render an opinion on specific causation. (Chapman Dep. 68, 209-10). For example, although Dr. Chapman asked Plaintiff to provide her with all of his medical records, Plaintiff provided her with only a small subset of his records from 2005-06. (Chapman Dep. 68-70, 141-42; Ex. 6, medical records provided by Plaintiff to Chapman). Plaintiff also refused Dr. Chapman’s request that he undergo an independent medical examination. (Chapman Dep. 69, 209). In addition, Plaintiff denied Dr. Chapman’s request to talk to Plaintiff’s physicians, ex-wife, and ex-girlfriends.

(Chapman Dep. 73, 207-08). He also ignored Dr. Chapman's request to see his divorce records. (Chapman Dep. 209).

In fact, it appears that Dr. Chapman learned more about this case *during* the deposition than she did *before* the deposition. For example, although Dr. Chapman had been under the impression that Plaintiff's alleged hypersexuality drove away his wife, Dr. Chapman learned during the deposition that Plaintiff sought a restraining order against his wife because his wife was violent and that Plaintiff had asked his wife for a divorce. (Chapman Dep. 159-62; Ex. 7, Plaintiff's Florida court records). Dr. Chapman conceded that these facts were "fundamentally different" than what Plaintiff had told her. (Chapman Dep. 162). Dr. Chapman also learned during the deposition that Plaintiff went back on Mirapex in 2006. (Chapman Dep. 270-75). She agreed that this fact was inconsistent with Plaintiff's claims in this case. (Chapman Dep. 270) ("Q: You know that in 2006 he went back on Mirapex? A: I did not know that. Q: That would be rather surprising for you if there is any truth to anything he's told you, wouldn't you agree? A: Yes.").

F. Dr. Chapman's specific causation opinion is unreliable because she does not account for the lack of a dose-response relationship between Plaintiff's use of Mirapex and his alleged hypersexuality.

Dr. Chapman opines that Mirapex caused Plaintiff's alleged hypersexuality because the hypersexuality started approximately three weeks after Plaintiff started taking Mirapex in 2005. (Chapman Report at 10, 11). As an initial matter, such a temporal relationship is insufficient to establish specific causation. *See,*

e.g., *Haller v. Astrazeneca Pharmaceuticals LP*, 598 F. Supp. 2d 1271, 1301 (M.D. Fla. 2009) (“merely demonstrating a temporal connection between a drug and a disease diagnosis is insufficient to prove a causal connection”). In any event, when Dr. Chapman wrote her report, she was unaware that in 2001 Plaintiff took Mirapex for six weeks at the same dose as his 2005 regimen, and that he experienced no compulsive behaviors at that time. (Chapman Dep. 146-153; Ex. 8, medical records). Dr. Chapman conceded that in determining whether Plaintiff’s hypersexuality in 2005 was caused by Mirapex, it would be important to know whether Plaintiff had experienced similar behavior when taking the same dose of Mirapex prior to 2005. (Chapman Dep. 148).⁷ Moreover, Dr. Chapman could not offer a biological explanation why Mirapex would cause Plaintiff to become hypersexual in 2005 when it did not do so in 2001. *See* Chapman Dep. 154 (“Q: And there is no biological explanation you can offer me at this point to explain if Mirapex had anything to do with his behavior in 2005 why it didn’t have that effect in 2001? A: No.”).⁸

When courts “analyze an expert’s methodology” in pharmaceutical product liability cases, they “should pay careful attention to the expert’s testimony about the dose-response relationship.” *McClain v. Metabolife Intern., Inc.*, 401 F.3d

⁷ At his deposition, Plaintiff testified that he did not experience increased sexual urges before 2005. (Ex. 8, Scelta Dep. 335, 338-39).

⁸ Dr. Chapman noted that Plaintiff was on additional medications “on top of the Mirapex” in 2005 and that this “could make a difference,” but she then quickly added that “I’m not a pharmacist. I’m not a neurologist.” (Chapman Dep. 153).

1233, 1241 (11th Cir. 2005). The “link between an expert’s opinions and the dose-response relationship is a key element of reliability” in such cases, and an expert “casts suspicion on the reliability of his methodology” when he ignores the dose-response relationship “without justification.” *Id.* at 1241 n.6, 1242. Because Dr. Chapman cannot explain why Plaintiff’s use of Mirapex for three weeks in 2005 caused him to become hypersexual while his use of Mirapex at the same dose for six weeks in 2001 did not cause such behavior, Dr. Chapman’s specific causation opinion is unreliable.

III. CONCLUSION

For the reasons stated above, defendants respectfully request that this Court exclude the testimony of Plaintiff’s general and specific causation expert, Dr. Heather Chapman.

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